



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0966]

Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following virtual public meeting entitled “Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages.” The purpose of the public meeting is to discuss the scope of the Closer to Zero action plan as it relates to the impacts of toxic element exposure and nutrition at different crucial developmental stages, including discussion of the key nutrients in food for growth and development, foods commonly consumed by babies and young children, and exposure risks of toxic elements.

DATES: The public meeting will be held on November 18, 2021, from 10 a.m. to 4 p.m. Eastern Time. FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0966. The docket will close on December 20, 2021. Submit electronic or written comments on this public meeting by December 20, 2021. See “Participating in the Public Meeting” in the SUPPLEMENTARY INFORMATION section of this document for closing dates for advanced registration and other information regarding meeting participation.

ADDRESSES: Due to the impact of the COVID-19 pandemic, this meeting will be held virtually to help protect the public and limit the spread of the virus.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 20, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of December 20, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0966 for “Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: *For general questions about the public meeting or for special accommodations due to disability:* Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On April 8, 2021, FDA announced the Closer to Zero (C2Z) action plan (available at: <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods#Introduction>) for reducing exposure to toxic elements from foods for babies and young children (see “FDA Releases Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies, Young Children,” available at: <https://www.fda.gov/news-events/press-announcements/fda-releases-action-plan-reducing-exposure-toxic-elements-foods-babies-young-children>). We have prioritized reducing exposure to toxic elements from foods for babies and young children because their smaller body sizes and rapid development make them more vulnerable to the harmful effects of these toxic elements. Exposure to toxic elements, including arsenic, lead, cadmium, and mercury, from foods depends on the levels of the elements in the food and the amount of the food consumed. Nutrient exposures can interact with the uptake of these elements and the nutrient status of children can modulate the effects of these elements.

The levels of toxic elements in foods depend on many factors, including:

- The levels of these elements in the air, water, and soil used to grow the crops, which vary depending on factors such as geographical differences and past or current contamination,
- The type of food crop and how much “uptake” there is of specific elements from the environment, and

- Industrial, manufacturing, and agricultural processes.

The C2Z action plan sets forth our approach to reducing exposure to toxic elements in foods commonly eaten by babies and young children to the lowest possible levels. FDA's goal is to reduce the levels of arsenic, lead, cadmium, and mercury in these foods to the greatest extent possible without setting levels that are not currently feasible and without reducing the availability of nutritious, affordable foods on which many families rely. The C2Z action plan outlines a multi-phase, science-based iterative approach to achieving our goal of getting levels of toxic elements in food closer to zero over time.

Closer to Zero includes research and evaluation of changes in dietary exposures to toxic elements, setting action levels (recommended limits of toxic elements in foods that can be achieved by industry and progressively lowered as appropriate), encouraging adoption of best practices by industry, and monitoring progress.

II. Purpose and Format of the Public Meeting

We are holding our first C2Z action plan meeting to get stakeholder input regarding the plan's scope. We will discuss foods commonly consumed by babies and young children, the impacts of toxic element exposures at different crucial developmental stages, and the interaction of nutrients and nutrient status as co-exposures to lead, arsenic, cadmium, and mercury on growth and development.

We will outline the C2Z plan including FDA's four-stage approach for continual improvement and additional work related to levels of toxic elements in food. Stakeholder panels will provide perspectives on the various issues needed to fulfill the C2Z plan. We will provide an opportunity for questions as well as an opportunity for open public comment. We expect this meeting to be the first of several regarding the C2Z action plan.

III. Participating in the Public Meeting

Registration: Registration is free and early registration is recommended. To register to attend the public meeting on "Closer to Zero Action Plan: Impacts of Toxic Element Exposure

and Nutrition at Different Crucial Developmental Stages,” by webcast, please register at <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops> by November 12, 2021 at 11:59 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted and will be provided the webcast link.

Table 1 provides information on participation in the public meetings.

Table 1 - Information on Participating in the Public Meeting and on Submitting Comments to Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages for Babies and Young Children

| Activity | Date | Electronic Address | Other Information |
|---|--------------------------------------|---|---|
| Public Meeting | November 18, 2021 | Webcast information will be provided prior to the meeting | Webcast will have closed captioning |
| Advance Registration | By November 12, 2021 | https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops | There is no registration fee for the public meeting. Early registration is recommended |
| Request to make oral presentation | By November 1, 2021 | https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops | |
| Notice confirming opportunity to make oral presentation | By November 4, 2021 | | An FDA representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so |
| Submitting either electronic or written comments | Submit comments by December 20, 2021 | https://www.regulations.gov | See ADDRESSES for addition information on submitting comments |

Requests for Oral Presentations: During online registration, you may indicate if you wish to present oral comments during the public comment session, and you may indicate which topic(s) you would like to address. FDA will do its best to accommodate requests to make public comments. We seek a broad representation of ideas and issues presented at the meeting.

All requests to make oral presentations must be received by November 1, 2021, 11:59 p.m. Eastern time. We urge individuals and organizations with common interests to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each presentation is to begin, and we will select and notify participants by November 4, 2021. Typically, presentations are between 3 and 5 minutes. No commercial or promotional

material will be permitted to be presented at the public meeting. Actual presentation times may vary based on how the meeting progresses in real time.

An agenda for the public meeting and any other background materials will be made available at least 5 days before the meeting at <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops>. Those without internet or email access can register and/or request to participate by contacting Juanita Yates (see FOR FURTHER INFORMATION CONTACT) no later than November 1, 2021.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov> and <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops>. You may also view the transcript at the Dockets Management Staff (see ADDRESSES).

Dated: October 5, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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